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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/242,977	02/26/99	WILSON J	GNVPN.019BUS

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EXAMINER	
MARTIN,J	
ART UNIT	PAPER NUMBER
1632	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FINE

Office Action Summary	Application No. 09/242,977	Applicant(s) Wilson et al.
	Examiner Jill D. Martin	Group Art Unit 1632

☒ Responsive to communication(s) filed on *Jan 24, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *7 and 16-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *7 and 16-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4, 6, & 7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants' Preliminary Amendment filed September 3, 1999 (Paper No. 3) has been entered. Claims 1 and 2 have been canceled, claims 3-6 have been amended, and claims 11-15 have been added. Applicants' Second Preliminary Amendment filed January 24, 2000 (Paper No. 5) has been entered. Claims 2-6 and 8-15 have been canceled, and claims 16-22 have been added. Claims 7 and 16-22 are pending and are under current examination.

Drawings

Applicants' Drawings filed February 26, 1999 have been approved by the Draftsman.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7 and 16-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,866,552. Although the conflicting claims are not identical, they are not patentably distinct from each other because

both sets of claims are directed to a method for expressing a transgene in a skeletal muscle cell by introducing an adeno-associated viral vector comprising the transgene to the cell such that the transgene is expressed in the cell in the absence of a cytotoxic immune response, and wherein the adeno-associated virus is substantially free of contamination with a helper virus. Furthermore, claims 16-22 of the instant application are directed to an AAV vector comprising an Apo E gene, and claim 3 of the '552 Patent specifically recites this embodiment as well as the '552 specification suggests the construction of AAV-ApoE (see columns 5 & 7). As such, the claims of the '552 Patent make obvious the instantly claimed method and AAV vectors comprising the Apo E gene.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16, 17, 19, 20, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Gouras et al. (Neurobiology of Aging, 1996).

Gouras et al. teach the construction of an AAV vector comprising the gene encoding Apo E under control of the CMV promoter. As such, the AAV vector of Gouras et al. meet all of the limitations of the claims.

Accordingly, Gouras et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Podsakoff et al. (Ref AI of Paper No. 6).

Claim 7 is directed to a method for expressing a transgene in a skeletal muscle cell using AAV which is substantially free of contamination with helper virus, wherein expression occurs in the absence of a cytotoxic immune response to the cell.

Podsakoff et al. teach a method of expressing genes of interest in skeletal muscle cells. See Examples 2 & 4. Podsakoff et al. teach an assay for purification of AAV virions away from contamination adenovirus. See paragraph bridging columns 18 & 19. Podsakoff et al. teach that gene expression lasts for up to 12 weeks *in vivo*. As such, the method of Podsakoff et al. meet all of the limitations of the claims. Note that the limitation "in the absence of a cytotoxic immune response directed against the cell" is an inherent feature of the purification assay of Podsakoff et al.

Accordingly, Podsakoff et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Podsakoff et al. (Ref AI of Paper No. 6) taken with Chiorini et al. (Ref AAB of Paper No. 7).

Claims 16-22 are directed to an AAV vector comprising the gene encoding human Apo E.

Podsakoff et al. specifically teach the construction of an AAV vector which harbors a DNA molecule of interest bound by AAV ITRs and additionally comprises promoters of interest such as CMV, RSV, etc. See columns 10 & 11. Podsakoff et al. teach use of therapeutic genes such as the EPO gene, and specifically discuss the use of other genes of interest which encode proteins for treatment of diseases such as hypercholestemia. Podsakoff et al. differ from the claimed invention in that they do not specifically teach the construction of an AAV vector comprising the human ApoE gene. However, at the time the claimed invention was made, the use of the Apo E gene in viral vectors was well known in the art as represented by Chiorini et al. who teach the construction of an AAV vector system which comprises genes of interest such as Apo E (column 3, line 14) as well as inducible promoters such as the metallothionein promoter (Claim 3).

Accordingly, in view of the teachings of Chiorini et al., it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to modify the AAV vector of Podsakoff et al. by substituting the Epo gene with the gene encoding human Apo E with a reasonable expectation of success. One of ordinary skill in the art would have been sufficiently motivated to make such a modification as it was an art-recognized goal to use AAV to deliver genes of interest under the control of promoter of interest as represented by both Podsakoff et al. and Chiorini et al.

Therefore, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill Martin whose telephone number is (703)305-2147.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine C. Chambers, can be reached at (703)308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Jill D. Martin

Patent Examiner